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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/237,969	01/27/1999	DAVID ALEXANDER	IMMR-023/01US	6872
22903	7590	12/03/2003	EXAMINER	
COOLEY GODWARD LLP ATTN: PATENT GROUP 11951 FREEDOM DRIVE, SUITE 1700 ONE FREEDOM SQUARE- RESTON TOWN CENTER RESTON, VA 20190-5061			SOTOMAYOR, JOHN	
			ART UNIT	PAPER NUMBER
			3714	

DATE MAILED: 12/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/237,969

Applicant(s)

ALEXANDER ET AL. *cd*

Examiner

John L. Sotomayor

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) newly added claims 174-200 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 174-200 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8, 15, 16. 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. In response to the amendment filed September 15, 2003, claims 1-173 are cancelled and newly added claims 174-200 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 185 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's specification discloses that a mock anatomical site is "pivotable to simulate various patient orientations". This language does not support the claim of "a pivoting mechanism" as shown in the claim and thus is new material not supported by the specification.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 196 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim discloses a "capture mechanism is configured to engage at least one nested instrument of a plurality of nested instruments and does not engage at least one nested

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instrument from the plurality of nested instruments” causing confusion about the intention of the action of the claim and rendering the claim indefinite.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 174, 176-177, 182, 185-186, 190, 192-196 and 199 are rejected under 35 U.S.C. 102(e) as being anticipated by Bailey (US 5,800,179).

Regarding claims 174 and 190, Bailey discloses an apparatus and method with a housing, a mock anatomical site with a pivotable orifice for receiving a peripheral. Applicant’s specification discloses that the housing and orifice of the mock anatomical site are “pivotable to simulate various patient orientations”. Bailey discloses a mock anatomical site that is pivotable

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by this definition in figure 1. Bailey also discloses a capture mechanism for engaging said peripheral to enable said interface apparatus to measure manipulation of said peripheral, and a sensing assembly to measure and transmit performance information from simulated medical procedure performed with the medical instrument (Col 3, lines 45-67, Col 4, lines 9-14 and figure 1).

Regarding claims 176, 182 and 192, Bailey discloses an apparatus and method in which a nested instrument assembly simulates a plurality of medical instruments in the instrument assembly each selectively manipulable by the user, a plurality of capture mechanisms to engage the nested instruments, and a sensing assembly to enable the simulation system to simulate performance of a medical procedure with the nested instrument assembly (Col 5, lines 23-37 and Col 6, lines 25-37).

Regarding claim 177, Bailey discloses an apparatus and method in which force feedback is applied in response to control signals from the simulation system (Col 3, lines 45-67).

Regarding claim 185, Bailey discloses an apparatus and method with a housing defining an orifice corresponding to a mock anatomical site and configured to receive a peripheral device (Fig 1), means to pivot the mock anatomical site to simulate various patient orientations and a sensing assembly configured to detect a manipulation of a received peripheral device (Col 5, lines 9-48).

Regarding claim 186, Bailey discloses an apparatus and method with a housing defining an orifice configured to receive a nested peripheral device having a plurality of nested instruments (Col 5, lines 8-22), a plurality of sensing assemblies each uniquely associated with

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the plurality of nested instruments and a plurality of peripheral motion assemblies configured to engage a first nested instrument and pass a second nested instrument (Col 5, lines 37-64).

Regarding claim 193, Bailey discloses a method of providing an output terminal configured to output the sensor signal to a simulation system further configured to simulate an endoscopic procedure (Fig 1 and Col 5, lines 1-22).

Regarding claim 194, Bailey discloses a method of surgical training wherein the mock anatomical site is configured to receive a working channel peripheral device being configured for use with an endoscope (Col 5, lines 5-37).

Regarding claim 195, Bailey discloses a method of surgical training wherein the mock anatomical site is configured to receive a navigation tube, the navigation tube having an end portion corresponding to a medical instrument (Col 7, lines 1-18).

Regarding claim 196, Bailey discloses a method of surgical training wherein the capture mechanism is configured to engage one or a plurality of nested instruments (Col 5, lines 5-22).

Regarding claim 199, Bailey discloses a method of surgical training with an orifice corresponding to a mock anatomical site and configured to receive a peripheral device (Fig 1), means to pivot the mock anatomical site to simulate various patient orientations, a sensing assembly configured to detect a manipulation of a received peripheral device (Col 5, lines 9-48) and providing force feedback via an actuator based upon the detected manipulation of the engage peripheral device (Col 6, lines 38-63).

Claim Rejections - 35 USC § 103

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6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 175, 178-181, 183, 187-189, 191, 197, 198 and 200 rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey.

Regarding claims 175, 178 and 191, Bailey discloses an apparatus and method for surgical training wherein the peripheral device corresponds to an endoscope (Col 5, lines 14-16). Bailey does not specifically disclose that the endoscopic device corresponds to a mock endoscope. However, Bailey discloses a mock anatomical site as a simulation of a real anatomical site. Therefore, it would have been obvious to one of ordinary skill in the art to use a mock endoscope as an equivalent device should a real endoscope not be available for the purposes of providing uninterrupted training experience for students.

Regarding claims 179-181, Bailey discloses an apparatus and method for surgical training with a working channel and peripheral device (Col 5, lines 38-49), a sensor configured to detect a movement of the working channel peripheral device (Col 6, lines 50-64), an actuator

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configured to apply force feedback based on detected movement of the peripheral device (claim 180 and 181) (Col 7, lines 19-26), and a navigation tube configured to traverse a simulated anatomy of a patient (Col 7, lines 18-40). Bailey does not specifically disclose that the endoscopic device corresponds to a mock endoscope. However, Bailey discloses a mock anatomical site as a simulation of a real anatomical site. Therefore, it would have been obvious to one of ordinary skill in the art to use a mock endoscope as an equivalent device should a real endoscope not be available for the purposes of providing uninterrupted training experience for students.

Regarding claims 183, 184 and 197, Bailey discloses an apparatus and method for surgical training with a mock anatomical assembly in which an instrument may be inserted and removed (Fig 1) and a sensing assembly for tracking the inserted instrument (Col 5, lines 23-30). Bailey does not specifically disclose a sensing assembly configured to detect insertion and removal of the peripheral device. However, it would have been obvious to one of ordinary skill in the art to provide a sensing means to detect trigger events such as the inserting and removal of the instrument for the purposes of proper update for the student simulation.

8. Claims 187-189, 198 and 200 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey in view of Tuason (US 5,403,191).

Regarding claims 187 and 189, Bailey discloses an apparatus and method for surgical training. Bailey does not specifically disclose a plurality of sensing assemblies being configured to detect a manipulation of a received peripheral device. However, Tuason teaches a surgery simulation and method with a plurality of devices and sensing assemblies used to simulate and detect the manipulation of a plurality of surgical devices (Col 5, lines 24-47 and Fig. 1).

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Therefore, it would have been obvious to one of ordinary skill in the art to provide an apparatus and method for surgical training as disclosed by Bailey with a plurality of sensing assemblies being configured to detect a manipulation of a received peripheral device as taught by Tuason for the purposes of providing a more life-like simulation of a surgical field for training students.

Regarding claim 188, Bailey discloses an apparatus and method for surgical training that includes a rotational motion sensor and a translational motion sensor means (Col 5, lines 25-30).

Regarding claim 198, Bailey discloses an apparatus and method for surgical training. Bailey does not specifically disclose the inserting, engaging and removal of a first peripheral device followed by an inserting, engaging and removal of a second peripheral device in combination with the detecting of said exchange used to simulate the exchange of medical instruments during a medical procedure. However, Tuason teaches a surgical training method in which a plurality of peripheral devices are inserted, engaged and, variously, removed to simulate the exchange of medical instruments during a real-life medical procedure (Col 7, lines 55-66). Therefore, it would have been obvious to one of ordinary skill in the art to provide an apparatus and method for surgical training as disclosed by Bailey with a surgical training method in which a plurality of peripheral devices are inserted, engaged and, variously, removed to simulate the exchange of medical instruments during a real-life medical procedure as taught by Tuason for the purposes of providing a real-life surgical field experience for a student.

Regarding claim 200, Bailey discloses an apparatus and method for surgical training including providing a mock anatomical site and a capture mechanism to engage a peripheral device to a sensing assembly. Bailey does not specifically disclose providing a resiliency-providing material disposed between the orifice and the sensing assembly. However, Tuason

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teaches that object simulated organs are made of a resiliency-providing material such as foam to more properly simulate the inserting of a peripheral into a human organ (Col 5, lines 55-60).

Therefore, it would have been obvious to one of ordinary skill in the art to provide an apparatus and method for surgical training including providing a mock anatomical site and a capture mechanism to engage a peripheral device to a sensing assembly as disclosed by Bailey with object simulated organs are made of a resiliency-providing material such as foam to more properly simulate the inserting of a peripheral into a human organ as taught by Tuason for a realistic feel when manipulating the organ objects with a peripheral during a training session.

Response to Arguments

Applicant's arguments with respect to claims 174-200 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Green (US 6,223,100) for a discussion of an apparatus and method for performing computer enhanced surgery with an articulated instrument.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John L Sotomayor whose telephone number is 703-305-4558. The examiner can normally be reached on 6:30-4:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom Hughes can be reached on 703-308-1806. The fax phone number for the organization where this application or proceeding is assigned is 703-746-8361.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-4558.

jls
November 25, 2003


S. THOMAS HUGHES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700